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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/939,161      | 08/24/2001  | Richard W. Voellmy   |                     | 4118             |

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/939,161

Applicant(s)

VOELLMY, RICHARD W.

Examiner

Simon J. Oh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

The election requirement of 01 October 2002 has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 16, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (U.S. Patent No. 5,830,177)

The Li *et al.* patent teaches compositions and treatment methods useful for the prevention of hair loss during chemotherapy. In a preferred embodiment, a nucleic acid comprising an expression vector capable of expressing human p-glycoprotein is administered to a subject (See Column 4, Lines 39-62). Methods of administration include the use of various carriers and incorporation into liposomes (See Column 5, Lines 16-23). Other methods of administration also include the utilization of electromagnetic radiation, including infrared radiation (See Column 5, Lines 58-66).

### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* in view of Jimenez *et al.* (U.S. Patent No. 5,486,509)

The Li *et al.* patent teaches compositions and treatment methods useful for the prevention of hair loss during chemotherapy. In a preferred embodiment, a nucleic acid comprising an expression vector capable of expressing human p-glycoprotein is administered to a subject (See Column 4, Lines 39-62). Methods of administration include the use of various carriers and incorporation into liposomes (See Column 5, Lines 16-23). Other methods of administration also include the utilization of electromagnetic radiation, including infrared radiation (See Column 5, Lines 58-66).

Li *et al.* does not teach the administration of a method of treatment for the prevention of chemotherapy-induced alopecia between 2 and 24 hours before administration of a chemotherapeutic drug.

Jimenez *et al.* teaches methods of inhibiting chemotherapy-induced alopecia (See Abstract). Compositions to be used with the treatment may include various carriers, diluents, and excipients, as well as penetration enhancing agents (See Column 3, Lines 43-52; and Column 4, Lines 1-8). Treatments for the prevention of chemotherapy-induced alopecia preferably administered once or twice daily beginning 5 to 8 days prior to the administration of a chemotherapeutic agent (See Column 4, Lines 13-31; and Examples).

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It would be obvious to one of ordinary skill in the art to combine the teachings of *Li et al.* and *Jiminez et al.* into the objects of inventions of the rejected claims. One of ordinary skill would be motivated to combine the disclosures of the *Jiminez et al.* with those of *Li et al.* because one of ordinary skill in the art would seek to give a treatment subject sufficient time to build up a resistance to chemotherapy-induced alopecia before the administration of any chemotherapeutic drugs. To one of ordinary skill in the art, it would be expected that without this preparation time, such a method of preventing alopecia might be insufficient.

Furthermore, the examiner does not see a patentable distinction between the applicant's selection of an activated HSF1 in nucleic acid or protein form and the disclosure in *Li et al.* of the administration of a nucleic acid comprising an expression vector capable of expressing human p-glycoprotein. The examiner shifts the burden onto the applicant to provide a showing of criticality or of results unexpected to one of ordinary skill in the art.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjo  
February 24, 2003

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
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